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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/049,419 | 02/12/2002 | Takanari Tominaga | 1422-0514P | 1153 |

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| EXAMINER | |
|---|---|
| MAIER, LEIGH C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/049,419 | TOMINAGA ET AL. | |
| | Examiner | Art Unit | |
| | Leigh C. Maier | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33-44 and 49-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-44 and 49-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 23, 2004 has been entered.

Claims 33, 39, and 49-52 have been amended. New claims 53-60 have been added. Any rejection or objection not specifically repeated has been withdrawn.

### *Claim Objections*

Claims 54 and 55 recite " the effective ingredient." The apparent antecedent to this limitation in claim 53 is "fucoidan." It is suggested that in order to eliminate any ambiguity in the claims, " the effective ingredient" be amended to "the fucoidan."

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites "wherein the allergic disease is a disease requiring suppression of IgE production." It appears that perhaps this claim is meant to limit the *method* to the treatment of an allergic disease is a disease requiring suppression of IgE production. If this is the case, the claim should be amended to recite "wherein the disease is an allergic disease [is a disease] requiring suppression of IgE production." As the claim stands, the independent claim is drawn to three classes of disease, but claim 37 only limits allergic disease, rendering the claim vague and indefinite.

Claim 54 recites a "daily dose of the effective ingredient." This appears to be a limitation aimed at a method of treating rather than a composition. Perhaps what Applicant intends is a composition wherein said composition is a unit dose. As recited, the claim is vague and indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 33-44 and 49-60 are rejected under 35 U.S.C. 102(a) as being anticipated by SAKAI et al (JP 2000-44602). Because the reference is in Japanese, the examiner is relying in part on the English abstract.

SAKAI teaches the treatment of bacterial infection, a disease condition requiring the regulation of cytokine production, by the administration of fucoidan (or a degradation product thereof) derived from *K. crassifolia*. The abstract is silent with regard to particular cytokines. However, the reference discloses administration of the required product to the required patient population. In doing so, the method is anticipated. The reference further teaches dosages with the recited range.

Claims 53-60 are rejected under 35 U.S.C. 102(e) as being anticipated by UMEDA et al (US 6,573,250)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

UMEDA discloses a composition comprising an effective amount (as defined by dependent claims) fucoidan derived from *K. crassifolia*. See col 13, lines 20-25. The description of the composition as a "cosmetic" is not limiting, as there is nothing in the disclosed composition that would preclude topical administration.

Claims 53-60 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by SAKAI et al (US 6,054,577) and under 102(b) as being anticipated by the corresponding reference, SAKAI et al (WO 96/34004). The citations refer to the US patent.

SAKAI discloses compositions comprising fucoidan and degradation products thereof. See example 6. The process described therein begins with a 2.5% solution of fucoidan derived from *K. crassifolia* ultimately obtaining three fractions comprising enzymatically degraded products thereof. The claims are thus anticipated.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-44 and 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAKAI et al (WO 96/34004) and HOSHINO et al (JP 1-313433).

SAKAI teaches as set forth above. The reference further teaches that fucoidans from brown algae (Phaeophyta) have a variety of therapeutic utilities, such as anti-metastasis and anti-viral (HIV). The reference is a general teaching that fucoidans derived from Phaeophyta are functional equivalents in the treatment of disease requiring regulation of cytokine regulation. However, the reference does not exemplify the treatment of disease, but it is specifically suggested. See page 1. Neither does the reference teach dosage ranges.

HOSHINO teaches that fucoidans derived from Fucus vesiculosus have anti-HIV activity with dosages for adults of 0.1-10 g, depending on the method of administration. See abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fucoidan from any known source, such as those taught by SAKAI, as an anti-HIV agent. One of ordinary skill would reasonably expect success in using the SAKAI fucoidans for such treatment, as suggested by the reference, using the dosage range taught by HOSHINO because the fucoidans from Phaeophyta are taught to be functional equivalents.

Although the references are silent with regard to particular cytokines, the cytokine regulation appears to be the mechanism by which the agent acts upon a human when administered to the required patient population and would flow naturally from the suggestion of the prior art. The recognition the biological mechanism of a treatment is not the basis for patentability when the method of treatment itself is taught by the prior art.

Claims 33-44 and 53-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAKAI et al (WO 96/34004) and McCAFFREY et al (JP 1-313433).

SAKAI teaches as set forth above. The reference further teaches that fucoidans from brown algae (Phaeophyta) have a variety of therapeutic utilities. The reference is a general teaching that fucoidans derived from Phaeophyta are functional equivalents in the treatment of disease. See page 1. The reference does not exemplify the treatment of diseases requiring nitric oxide production.

McCAFFREY teaches that fucoidan derived from Fucus vesiculosus has antiproliferative activity useful for the treatment of atherosclerosis, a disease requiring nitric oxide production. See page 773 and paragraph bridging pages 777-778. The reference teaches dosages for rats of about 4-5 mg/day.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fucoidan from any known source, such as those taught by SAKAI, for the treatment of atherosclerosis. One of ordinary skill would reasonably expect success in using the SAKAI fucoidans for such treatment, as suggested by McMCAFFREY, because the fucoidans from Phaeophyta are taught to be functional equivalents. It would be within the scope

of the artisan to determine effective amounts for human administration starting with the doses taught by McMCAFFREY.

Although the references are silent with regard to particular cytokines, the cytokine regulation appears to be the mechanism by which the agent acts upon a human when administered to the required patient population and would flow naturally from the suggestion of the prior art. The recognition the biological mechanism of a treatment is not the basis for patentability when the method of treatment itself is taught by the prior art.

Claims 33-44 and 49-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over SAKAI et al (WO 96/34004) and LION CORP (JP 11-21247). Because the LION CORP reference is in Japanese, the examiner is relying in part on the Derwent abstract.

SAKAI teaches as set forth above. The reference does not exemplify the treatment of allergic disease.

LION CORP teaches that fucoidan extracted from algae such as Fucus vesiculosus is a skin activating and allergy inhibitory agent. See abstract and tables in the full reference.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fucoidan from any known source, such as those taught by SAKAI, for the percutaneous treatment of allergic diseases. One of ordinary skill would reasonably expect success in using the SAKAI fucoidans for such treatment, as suggested by LION CORP, because the fucoidans from Phaeophyta are taught to be functional equivalents. It would be within the scope of the artisan to determine effective amounts for human administration given the data provided by LION CORP.

Although the references are silent with regard to particular cytokines, the cytokine regulation appears to be the mechanism by which the agent acts upon a human when administered to the required patient population and would flow naturally from the suggestion of the prior art. The recognition the biological mechanism of a treatment is not the basis for patentability when the method of treatment itself is taught by the prior art.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33 and 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of U.S. Patent No. 6,593,311. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reference claim is drawn to a method for inducing apoptosis comprising the administration of a sulfated-fucose-containing polysaccharide (fucoidan) derived from a five-member group of algae including *K. crassifolia*. Induction of apoptosis would define a population of patients having cancer, a disease requiring cytokine regulation. It would be obvious to select a fucoidan from any of these algae, such as *K. crassifolia*.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier
Patent Examiner
April 2, 2004